

# Parallel Importation of Pharmaceuticals: When is international exhaustion an effective policy choice?

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**Parallel Importation of Pharmaceuticals:  
When is international exhaustion an effective policy choice?**

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## Abstract

National policy regarding parallel importation determines whether prices for a good protected by intellectual property rights are set in a segmented national market or in a larger international market. The innovative pharmaceutical industry has a cost structure which depends on patents and other intellectual property rights in order to recover the large sunk cost of research and development; parallel imports affect the ability of pharmaceutical firms to recover those costs. After discussing the international political context of parallel importation policy, international price differences, which create and are in turn affected by the possibility of parallel importation, are examined. Prices of name-brand pharmaceutical products are found to vary from the ideal of proportionality with income for several reasons, among them income inequality within a country. Applying simple theoretical assumptions about how prices are affected by the possibility of parallel importation, conditions are described under which allowing parallel importation can bring about price moderation. In other instances, parallel importation can have harmful external effects without bringing any benefit.

## Acknowledgements

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A nation's policy regarding the exhaustion of patent rights affects the structure of world-wide markets for goods protected by intellectual property rights. By choosing international exhaustion, a nation allows parallel importation of patented goods, arbitrage trade that could reduce price differences between different national markets. Alternately, by choosing national exhaustion, a nation disallows parallel importation, effectively segmenting its own markets from the rest of the world. Is a segmented market better than one tempered by the possibility of international arbitrage? The gut reaction of believers in international trade would probably be in support of the latter: trade is beneficial, isn't it?

The market for innovative pharmaceuticals is far from perfectly functioning, though; describing it even as a second-best world would be inaccurate by orders of magnitude. Institutions including public and private insurance bodies, patent and other intellectual property rights, health regulatory bodies, and international aid and trade organizations all work to control how pharmaceutical markets function, sometimes in concert and sometimes at odds with each other. This paper will examine one very particular policy choice, whether or not a nation should permit parallel importation, in the context of a market not described by the classic assumptions of international trade. Because parallel imports primarily affect prices, price levels of innovative pharmaceuticals will be examined, comparing the theoretical ideal with the empirical reality.

Parallel importation policies have important consequences on a number of dimensions. Governments wanting to control health care spending are interested in the possibility of using parallel imports to moderate drug prices. International bodies such as the World Health Organization are concerned that parallel imports could impede access to essential drugs in developing nations. With the signing of the treaty on Trade-Related Aspects of Intellectual

Property (TRIPS), the World Trade Organization demonstrated concern for global level of intellectual property protection and the incentives for innovation that such rights protect. The externalities created by parallel importation would seem to affect innovation incentives, but ultimately TRIPS made no attempt at international policy coordination, leaving parallel importation unregulated. Viewed strictly as a national policy choice, allowing parallel importation will be seen to have beneficial price-moderating effects only under a very limited set of circumstances.

The argument is organized as follows: section II describes the function of patents and other aspects of the research-based pharmaceutical industry; section III examines effects of parallel importation on the market; section IV places the decision regarding exhaustion policy in the context of the international treaty regarding intellectual property rights negotiated in the World Trade Organization; section V discusses ideal international price levels for pharmaceuticals; section VI examines empirical data on price levels and discusses why they deviate from the ideal; section VII explores the conditions under which allowing parallel importation can moderate prices; and section VIII concludes.

## **II. Patenting: paying for innovation**

The research-based pharmaceutical industry is heavily reliant on patents to protect incentives to research and develop new drugs. A patent is a mechanism for commodifying technological innovation, awarding the inventor of a new technology the right to production and marketing exclusivity for a limited period of time and giving the holder monopoly power over good embodying the technology. By limiting competition, thus allowing the good to be sold at a price greater than marginal cost, patent rights reward the inventor for the fixed costs incurred in

innovation.

The pharmaceutical industry is particularly reliant on patents because the fixed costs of drug R&D are very large compared to marginal production costs; current estimates stand as high as eight hundred million dollars for the development of a new pharmaceutical product (DiMasi *et al.* 2003). Marginal production costs are so low that drugs could easily be imitated were they not protected by patents; for example, India, which does not offer patent protection for pharmaceuticals, has built an industry around producing generic copies of on-patent drugs. Research-based companies spend hundreds of millions of dollars to bring new drugs to market, costs which they are able to recoup only because of the exclusive marketing rights provided by patents.

Patents represent a balance between allocative and dynamic efficiency, sacrificing low prices for more innovation. In the global economy, how to properly distribute the burden of innovation—the allocative inefficiencies that, in a sense, pay for new technology—is a vital question, particularly in such important areas of technology as medicines. The products of innovation are essentially public goods, the benefits of which are not contained by national borders.

However, the strength of patent protection, which represents both an inefficiency burden and an incentive for future innovation, is determined by a range of national and international policy choices, the latter largely embodied in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). Among policy options, the choice of an exhaustion regime determines the international structure of industries dependent on patents, affecting drug prices and rents to pharmaceutical firms. As TRIPS was being formulated, standardizing an international policy on exhaustion was debated; arguments were made in favor

both of national and international exhaustion, but ultimately, exhaustion policy was left as a national prerogative.

### III. Parallel Importation and the Exhaustion of Patent Rights

Parallel importation occurs when a patented, trademarked or copyrighted good, legitimately sold in one country, is imported into another country where the same good is protected by intellectual property laws. It is not an issue of piracy, because the good must either be produced by or under license from the original patent holder. Rather, parallel importation concerns the *exhaustion* of intellectual property rights. Allowing parallel importation means that a patent holder's right to distribute a good is exhausted internationally once it is placed on a market; thus when a good is marketed in a foreign country, the patent holder has no right to regulate the resale of the good domestically. If parallel importation were prohibited (a policy of national exhaustion), then the national market would be segmented and varying prices for the same patented good would be observed across countries; if parallel importation were allowed, arbitrage could take place if the price of the same good varies across countries. The possibility of arbitrage could have two main effects. First, it could discourage investment in informational marketing and monitoring services in the importing country. Second, it could link markets together, making the price in any country dependent not just on local demand conditions, but also on prices in other countries.

Pharmaceutical companies spend large amounts to market their drugs to consumers and institutional buyers and monitor the quality of their products. Allowing parallel importation could destroy the incentive to make such investments, because importers could essentially free-ride on the investments of authorized sellers. The marketing efforts of pharmaceutical

companies represent a larger portion of expenditures than do investments in research and development, and provide information about pharmaceutical products which many doctors use in making prescription decisions. Schweitzer (1997) discusses various types of marketing efforts, some of which provide information about specific drugs and promote particular products, while others promote the corporate reputation by sponsoring continuing medical education for physicians. All types of marketing are highly regulated in the United States and Europe. Pharmaceutical companies are unable to control the quality of parallel imported drugs and therefore fear that their brand reputation may suffer if they are allowed. Additionally, because parallel importers would benefit from many informational marketing by brand-name firms without contributing to its cost, the return to such marketing would decrease. Beyond informational advertising, Maskus (2001) speculates that competition from parallel importers might also lead to excessive efforts at product differentiation. These effects are basically national in scope; other effects of allowing parallel importation are not limited by national borders.

A single country's policy on parallel importation could also have external effects on its trading partners, by making prices in any country dependent on more than local demand conditions. The possible external effects of allowing parallel importation may easily be seen in a simple two-country model, where country A is high-income and country B is low-income<sup>1</sup>. If a pharmaceutical firm is allowed to price discriminate between the two countries, the firm chooses the profit-maximizing price level appropriate for each country. Under segregation, price in country A will then be higher than price in country B. Note also that the rent from the patent, and therefore the country's contribution to global innovation incentives, is independently

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<sup>1</sup>This discussion follows the numerical model in Maskus (2001).



determined in each country.

Suppose then that country A chooses a regime of international exhaustion, allowing parallel importation of the drug from lower-priced country B. In the absence of trade costs and price regulation, the potential for competitive arbitrage will force the firm to set a single price in both countries, chosen to maximize profit across total demand for the drug. This single price will be higher than the discriminatory price in country B, and lower than the discriminatory price in country A; the total rent collected by the firm in each country is also lower than under discrimination. A policy choice in country A lowers its price and its innovation incentives, while raising the price and *lowering* innovation incentives in country B.<sup>2</sup> Conceivably, it may be more profitable for the firm to offer the drug at the original price level, making it affordable only in country A, than it would be to offer it at a lower price in both countries; A's policy choice could lead to the market in B going entirely unserved, or a price that is higher than optimal for dynamic efficiency. Because price in country B is initially lower, its choice of exhaustion regime is irrelevant. Such a situation seems to call for international policy coordination, which the WTO considered but ultimately left undecided in TRIPS.

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<sup>2</sup>Profits in country B are lowered by country A's policy choice if the autarkic price in country B was profit-maximizing, which may not always be the case.

#### IV. The International Context of TRIPS

*The world is undertaking an unprecedented experiment: to accelerate the introduction of higher standards in regions that would not ordinarily be expected to adopt them.*

-Keith Maskus (2000, p. 144)

In 1994, the newly created World Trade Organization (WTO) established international minimum standards for intellectual property rights protection, codified in the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Concerning patents, TRIPS requires all WTO member countries to provide at least twenty years of protection, as well as to recognize numerous conditions on how national patent laws may be formulated. Since in some instances, the agreement requires the establishment of entirely new institutions to grant and regulate patenting, a transition period was established, allowing more time for less developed countries to institute the required reforms.

Maskus (2000) characterizes TRIPS as an unprecedented experiment because most countries have instituted patents only after reaching a certain level of economic and technological development, and have recognized intellectual property rights internationally later still. That developing countries might benefit from higher standards of protection is a speculative claim, qualified by large short-run adjustment costs. In an attempt to quantify the short-run transfers of rents due to increased standards of protection, McCalman (1999) finds that the TRIPS will cause net transfers from developing countries, accruing largely to the United States.<sup>3</sup> Not surprisingly, many developing countries are reluctant to adopt stronger patent

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<sup>3</sup>McCalman models only the redistribution of rents between countries, assuming an

protection, fearing that the monopoly distortions created by issuing patents would raise prices on essential goods, such as pharmaceuticals.

Indeed, much attention has been given to the pharmaceutical industry in formulating the international regulations of TRIPS. The agreement allows an additional transition period for least developed countries to enforce patent protection for pharmaceuticals, and the subsequent Doha Declaration on Public Health acknowledges that TRIPS “should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.” Promoting access to medicines necessitates the proper balancing of patent rights; overly strong patent protection would lead to unaffordable medicines, while weak protection could stymie innovation and the creation of new medicines. Attempting to justify the increases in both the length of patents and the number of countries where protection is offered, it is often argued that developing countries should offer strong patent protection because countries have different disease burdens, and so different potential demands for pharmaceuticals. Strengthening patents in the developing world might therefore increase the incentive to research and develop treatments for tropical diseases which do not affect the developed world.

The economically ideal length of patent protection varies by individual product or industry, though the information necessary to determine that length is generally not available at the time a patent is awarded. Patent length, required by TRIPS to be at least 20 years and not allowed to vary by industry, is thus a very blunt instrument for balancing allocative and dynamic efficiency. In the pharmaceutical industry, developed nations use a range of policies to fine-tune the strength of patent protection and the potential profitability of a patented innovation. If there

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exogenous level of innovation in each country.

is free entry in drug research and development, innovation incentives can be controlled to alter levels of dynamic efficiency. <sup>4</sup> Since very few drugs have no therapeutic substitutes, some competition still exists; it is perhaps most helpful to think of a patent holder monopolizing on the residual demand for a drug.

Though TRIPS sets a minimum length of twenty years of protection for patented innovations, developed nations still have many other policy levers to control the incentives for pharmaceutical innovation. Local patent offices have control over the scope and breadth of patent innovation, and could allow patents to be rewarded for smaller, incremental innovations or only for larger breakthroughs. Drugs must undergo regulatory approval processes, which essentially determine the length of time which a drug can be marketed before generic entry — the effective length of the patent. Many countries directly or indirectly control the price of patented pharmaceuticals, as well, setting or negotiating the rents which accrue to an innovating pharmaceutical firm. TRIPS presents a great challenge to developing nations, whom may have yet to create the institutions to regulate patenting and develop policies to regulate innovation.

Allowing parallel importation is one simple policy choice which could reduce drug prices, but because of the possible externalities created by parallel importation, international regulation seems sensible as TRIPS was being negotiated. Debate was framed as a choice between a worldwide uniform ban or a uniform allowance of parallel importation. <sup>5</sup> However, the

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<sup>4</sup> Patent protection does not affect all innovation, because for-profit research and development firms contribute only one part of total R&D. Institutions such as research universities and government laboratories engage in much basic research for which patents may offer inadequate or inappropriate incentives.

<sup>5</sup> For various legal standpoints, see Barfield and Groombridge (1999), who argue in favor of banning parallel imports, and Abbott (1998b), who argues in favor of permitting them.

TRIPS agreement ultimately reflects a compromise which leaves the question unsettled. Article six of the agreement states and imply: "For the purposes of dispute settlement under this Agreement ... nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." The provision is limited only by the stipulations for national and most-favored nation treatment. The clause allows nations to formulate independent policies on parallel importation, which may even vary by industry, though TRIPS generally does not allow for the formulation of industry-specific intellectual property law.<sup>6</sup>

Currently, countries have implemented a variety of exhaustion regimes regarding pharmaceutical patent rights. The United States recognizes national exhaustion of pharmaceutical patents, and gives the patent holder the explicit right of importation.<sup>7</sup> Hong Kong, Israel, Singapore, Argentina, Thailand, and New Zealand all recognize international exhaustion, allowing parallel importation of patented pharmaceuticals. South Africa's allowance of parallel importation was the subject of a dispute with the United States beginning in 1997.<sup>8</sup> Japan allows parallel importation of pharmaceuticals only if the drugs are imported from unregulated markets. The European Union has instituted a policy of regional exhaustion, allowing parallel importation from nations within the union, but prohibiting it otherwise. The legal status of exhaustion is not clear in many developing countries; in some, it is not only prohibited, but the nation awards sole distributorship for pharmaceuticals to a single firm

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<sup>6</sup>The WTO Ministerial Declaration on TRIPS and Public Health, issued during the Doha round of trade negotiations, reconfirmed that exhaustion is a national policy choice (CIPR 2002).

<sup>7</sup>On a small scale, some parallel trade flows from Canada to the U.S. through internet pharmacies and busloads of senior citizens who cross the boarder to save money on their prescriptions, but this activity does not extend to the wholesale level.

(Correa 2001). Left to the individual nation, these policy choices on parallel importation might not account for external effects created by allowing international exhaustion of patent rights.

## **V. Ideal Drug Prices**

Much of the theoretical and policy debates surrounding parallel importation, including the simple model presented in section III, revolves around several characterizations of what drug prices would be if parallel importation were or were not allowed. First, it is assumed that, if national markets were segmented, a welfare-enhancing pattern of prices known as differential pricing would be observed. Because parallel importation would prevent market segmentation, the argument is often made that parallel imports should be banned in order to achieve differential pricing. Second, in a situation where national markets were segmented, prices would vary proportionally to per capita income levels in national markets. Under this characterization, higher-income nations would be taking advantage of lower-income nations if they use parallel imports to lower their drug prices. Finally, it is assumed that if parallel trade is allowed, arbitrage possibilities would cause drug prices to equalize to within transport margins. This section will examine these assumptions in detail and review literature relevant to the debate which makes use of them. The following two sections will discuss evidence concerning the validity of the assumptions.

The first characterization proposes that, if national markets were segmented, pharmaceutical firms would set price levels proportional to consumers' willingness to pay.

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<sup>8</sup>See <http://www.cptech.org/ip/fsd/health-pi.html> for a detailed review of the dispute.

Danzon(2001) explainsthatpricingbyamonopolistinasegregatedmarketwouldresemble Ramseypricing,wherethepriceforeachgroupofconsumerswouldbesetproportiona ltotheir demandelasticity.Nationswithahigherwillingnesstopaywouldbechargedahighermark -up overmarginalcost,andwouldthereforecontributemoretorecoveringthesunkcostsofdrug development.Ramsey -stylepricingpracticesarecommoni nindustrieswithhighjoint,sunk costsrelativetomarginalcosts,suchasairlinesandelectricutilities(Danzon1997).Differential pricingwouldpermitpharmaceuticalfirmstorecovertheirR&Dcosts,whilemaximizingtotal consumer andproducer surplusbyallowingmorepeopletobeservedthanunderasingle, commonmarketprice.Differentialpricingwouldalsotakeintoaccountdifferentpreferencesfor innovationacrosscountries.Varyinglevelsofpatentprotectionleadtodifferentlevelsof competitioninnationalmarkets.Inacountrywithweakerpatentrights,moresubstitutesfora patenteddrugwouldexist;consumerswouldthereforehavehigherpriceelasticity.Ifadrug manufacturerpracticeddifferentialpricing,pricesforthesecons umerswouldbelower,aswould theircontributiontodynamicefficiency.

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elasticity. In developing nations, public or private insurance coverage is not nearly prevalent, and drugs must be paid for out-of-pocket (Maskus 2002). However, if health care or insurance providers in high-income nations are able to leverage their monopsony power to negotiate discounts, as do managed care health plans in the United States, the negative correlation between income and price elasticity would no longer hold. Also, unlike strict Ramsey-style practices, where prices are inversely proportional to demand elasticity, pricing proportional to income would not account for differences in innovation preferences between countries.

Theoretical models of parallel importation policies typically assume a direct correlation between drug prices and income. In a frequently cited article, Malueg and Schwartz (1994) make use of the characterization that drug prices would be higher in higher income nations to argue against allowing parallel importation. They explore the static welfare effects of segmentation versus discrimination for different levels of demand dispersion. Disregarding dynamic effects from contribution to sunk costs, they find that consumers are still better off under discrimination if demand dispersion is high enough. Setting a single price would cause some markets to go unserved, even though consumers in those markets would be willing to pay a price higher than the marginal production costs; this is the standard inefficiency resulting from monopoly pricing. For a sufficiently wide dispersion of incomes across countries, the welfare loss from some consumers going unserved is greater than the welfare loss due to some consumers paying higher discriminatory prices. The authors point out that still higher welfare can be achieved by setting creating groups of consumers with different incomes, and allowing discrimination between but not within the groups.

Making use of the third characterization, that prices will equalize if parallel imports are allowed, Richardson (2002) and Knox and Richardson (2002) examine policy games which



allow countries to choose their parallel importation policy. Richardson (2002) describes a simple policy game in which governments choose to open to parallel importation if they would otherwise face a higher discriminatory price. The policy choices of countries that would face lower prices under segregation are essentially irrelevant to the resulting price levels; the set of equilibria in the game would all result in a single global price. In several extensions, this result is qualified using political economy considerations and the possibility of tariff policy. Tariffs affect transportation costs, the introduction of which complicates the repercussions of parallel imports. It is suggested that a country supplied by a foreign-based monopolist may find it more beneficial to prohibit parallel imports and levy a tariff to extract part of the monopolist's surplus than to open to parallel imports. Knox and Richardson (2002) examine the interaction of tariff policy and parallel imports in a two-country setting and find that allowing parallel importation results in a lower optimal tariff. Generally, parallel importation is more attractive for countries with little control over tariffs.

Richardson's exploration of policy choice games were motivated by a lack of congruence between expectations and reality. Malueg and Schwartz's model predicts that lower income nations would favor a worldwide prohibition of parallel imports in order to benefit from lower differential prices; during the negotiation of TRIPS, however, the opposite was the case. Many developing nations wanted to retain the ability to permit parallel importation, fearing that segmentation could lead to higher prices (Abbott 1998b). Turning to empirical evidence of price differences, the next section will shed light on why prices do not always vary proportionally with income.

## VI. Actual Drug Prices

Limited evidence exists that pharmaceutical firms may set prices proportional to income levels. Schut and Van Bergeijk (1986) make use of a report published by the United Nations International Comparisons Project to study the effects of various country characteristics and policy variables on drug prices. Using a dataset that includes observations from thirty-two developing and developed nations in 1975, they regress a purchasing-power parity price index of “Drug and Medicinal Preparations” on per capita GDP and a number of controls, and find a strong and significant positive relationship between prices and income levels. An 8% increase in drug prices is predicted to be observed with a 10% increase in GDP per capita. The authors take this finding as evidence that pharmaceutical firms practiced discriminatory pricing, “successfully creaming off the international consumer surplus.”

The policy variables examined offer an explanation for the deviation from income-proportionate prices. A dummy variable equal to unity if a government directly controlled the price of pharmaceuticals produces on average a 20% decrease in drug prices. A weaker and less significant effect is found for indirect price controls.<sup>9</sup> Offering patent protection for pharmaceutical products is found to have a positive but insignificant effect on price levels. Explaining the insignificant results, the authors note that dummy variables capture only crude effects. Different types of regulation can have crucially different effects on pricing strategies. Also, many policies interact to determine the true level of patent protection for pharmaceuticals; a binary variable does not adequately capture the amount of variation. Both direct price regulation and level of patent protection undoubtedly affect drug prices; as will be discussed

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<sup>9</sup>Indirect price controls include such regulations as the United Kingdom’s limit on

later, parallel importation may be able to decrease drug prices in situations where price regulations are ineffective or patent systems are overly strong.

In a more recent study, Scherer and Watal (2001) find a weak but significant relationship between income and drug prices. They examine data on the wholesale prices of fifteen different AIDS anti-retroviral drugs in eighteen nations between 1995 and 1999. Though all eighteen nations were low or middle income, with GNP's less than one third of the United States, prices were actually higher than U.S. list prices for 21% of the observations. In a regression of price levels (relative to the U.S.) of individual drugs on per capita GNP and several controls, they find a significant but weak relationship: an increase of \$1000 in income leads to an increase of only 0.018 in the price relative.

Besides controls for various drug characteristics, two other variables present interpretational difficulties. A dummy equal to unity if a country offered patent protection for drugs would be expected to have a positive effect on prices; instead, a small negative effect is observed. This anomaly is attributed to measurement difficulty in the variable, because information about whether the specific drug product was actually patented in a country was unavailable. The authors also explore changes in pricing patterns over the five years span of their dataset; two model specifications offer different interpretations. In one specification, a time trend is found to have a negative effect, suggesting that prices relative to the U.S. were uniformly decreasing over time. In another specification, the independent time trend is removed and a variable interacting the year with income per capita added. Here, income is initially found to have a small positive effect on prices, but the strength of the effect diminishes substantially over time. In 1995, an additional \$1000 in income was associated with an increase of .057 in the

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return to capital, which is set individually for each pharmaceutical firm

price relatives. By 1999, though, the same increase in income added only .006 to prices. The authors interpret the interaction term by suggesting that pharmaceutical firms may have moved away from a strategy of differential pricing between 1995 and 1999, making prices less correlated with income. However, it is unclear why the authors did not include a basic time trend in their second specification. Because the second regression has less overall explanatory power than the first, the interpretation that firms moved away from differential pricing strategies should be treated with some caution.

Data published in Maskus (2001) provides an additional opportunity to test whether pharmaceutical firms price proportionally to per capita income. The author examines the correlation between prices for individual drugs and per capita GNP, which would approach unity if differential pricing were practiced. The strength of the correlation varies depending on the drug examined; the prices of eight drugs have a correlation with income of at least 0.5, nine have a correlation between 0 and 0.5, and three have negative correlations. As in the other studies, prices deviate significantly from what one would expect under differential pricing.

Prices might be higher in lower income nations due to unequal income distributions. A firm may be unable to discriminate between consumers at various income levels within a national market, and so choose to set a high price and supply only a small group of high income consumers with relatively inelastic demand. If demand is kinked because different groups of consumers have very different income levels, firms may choose not to supply the low income, price-sensitive consumers within a country.<sup>10</sup> This strategy is actually still consistent with the most precise definition of Ramsey pricing, since firms set a price inversely proportional to

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<sup>10</sup>Maskus (2001) points out that such strategies are common in other industries where

consumers' demand elasticity. Because only a subset of the country is supplied, though, per capita income averaged over the entire country does not accurately proxy for the demand elasticity of the group of consumers actually being supplied.

To test whether prices are affected by unequal income distributions, I use the price data from Maskus (2001) to see if prices vary with a measure of income inequality, in addition to per capita income levels. The pricing data consists of 1998 per-dose ex-manufacturer's prices for 20 brand named drugs in 14 countries with a large range of incomes. Because the prices represent identical products sold by the owner of the brand name, methodological difficulties typical of international drug price comparisons are mitigated. Data on per-capita GNP is taken from the World Bank's World Development Indicators and measured at purchasing-power exchange rates to most accurately represent consumers' ability to pay. Income inequality is measured by national Gini coefficients, also published in the World Development Indicators. A Gini index of zero represents a perfectly equal distribution of income; an index of 100 represents perfect inequality, where all income is held by just one person. Two caveats should be noted about the comparability of the Gini index across countries. Because calculating the index requires detailed household level data on income, they are not available annually. The Gini indices for the fourteen countries in the dataset were recalculated between 1990 (Spain) and 1998 (Thailand, Mexico, and Brazil). Also, the indices for India, Korea, and Thailand were recalculated on the basis of consumption expenditures, while the others were recalculated using income. Still, they provide a rough measure of disparities in income within a nation that could lead to higher prices.

I test the hypothesis that prices are proportional to per-capita income, controlling for the effects of inequality and variation in prices between drugs. Instead of a single constant term, the

regression is run using twenty dummy variables, equal to unity if the drug name matches the name of the variable and zero otherwise. For a given drug, the ratio of price to GNP per capita should be constant if differential pricing is followed. Deviation from that constant could occur because of income inequality. Regression results are as follows, with the absolute value of t-statistics given in brackets:

$$\ln(\text{price}) = 0.675 \ln(\text{GNP per capita}) + 0.984 \ln(\text{gini})$$

[13.07]                      [9.44]

-10.62norvasc [13.71]	-10.05lipitor [12.77]	-11.74pulmocort [15.01]	-8.79sandimmun [11.12]	-8.66neoral [11.05]	
-9.48cipro [12.23]	-10.88plendil [14.04]	-11.42imovane [14.61]	-8.87diflucan [11.37]	-12.43lasix [15.94]	-10.82claritin [13.93]
-10.14cozaar [13.00]	-8.61zyprexa [11.01]	-9.56losec [12.24]	-10.85zeantac [13.99]	-9.80risperdal [12.65]	-10.00zoloft [12.80]
-10.05zocor [12.86]	-8.48imitrex [10.80]	-10.03effexor [12.77]			

$$R^2 = .901 \quad N = 234$$

Both per capita income levels and level of inequality have significant effects on drug prices. A 10% increase in income is associated with a 6.75% increase in prices; a 10% increase in inequality, as measured by the gini index, is associated with a 9.84% increase in prices, other things equal. These results suggest that pharmaceutical manufacturers may have been following a strategy of setting prices inversely proportional to demand elasticity, which is affected both by per-capita income levels and inequality within a country. The relationship between prices and income levels is comparable in strength to Schut and Van Bergeijk's findings, which made use of a price index, and much stronger than Scherer and Watal's result. The disparity may be explained partly because different types of drugs are examined. The dataset in Markusin includes

prices of drugs used to treat a variety of illnesses, whereas Scherer and Watalexamine the prices of AIDS drugs only, controlling for various drug characteristics but not for each individual drug.

Besides unequal distribution of income, price regulations may hinder pharmaceutical companies from pricing proportionally to income levels. As mentioned above, Schut and Van Bergeijk (1986) found crude evidence that direct price regulation lowers the price of pharmaceuticals. The actual distortionary effects of price regulation depend on how the particular system works, though. Danzon (1997) provides a detailed review of the wide variety of price regulatory systems worldwide; some countries set price ceilings using a cost-plus-markup formula, while others determine prices by referencing prices in other countries. National health insurance programs can give countries monopsony power, allowing them to negotiate for lower prices.

As an example of reference pricing, Canada does not allow prices to exceed the median of a set of prices in seven other developed countries; Saudi Arabia determines allowable prices using a formula that references forty countries.<sup>11</sup> The practice of reference pricing may have external effects on pharmaceutical prices in countries which are referenced, very similar to the effects of allowing parallel importation. If a lower income country is referenced by another country that regulates prices, a pharmaceutical company may set an artificially high price in the lower income market in order to raise the allowable ceiling in a higher priced market. Depending on the specification of the reference formula, one would expect higher drug prices in countries that are referenced.

This examination of pharmaceutical price levels has suggested several reasons why

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<sup>11</sup> See Schoonveld (2001) for an interesting graphical depiction of the web of

international differences exist. Pharmaceutical companies may be following a policy of differential pricing, where prices are inversely proportional to demand elasticity. A pattern of pricing proportional to income is observed, with differences in income inequality explaining variation from this pattern. Different levels of patent protection, pharmaceutical price controls and reference pricing practices further distort prices from differential levels. All these causes of international price differences create the opportunity for parallel importation, but parallel imports will be an effective tool for mitigating prices only under certain circumstances.

## VII. When will parallel imports be effective?

The size of price reductions achieved through parallel trade depends most basically on the size and elasticity of demand of the relevant markets. Pharmaceutical firms will try to protect their profits in larger markets, where allowing parallel imports will offer less opportunity for price reductions and create greater potential for externalities. Relatively smaller and more elastic markets could achieve greater price reductions through parallel importation.

The relationship of market size and price reductions through parallel imports can be seen in a numerical example, which differs from the discussion in section III by introducing trade costs. For a demand curve in country B,

$$(1) \quad x_B(p_B) = 10 - p_B$$

a price discriminating monopolist facing a constant marginal production cost of 2 will set a price in autarky of  $p_B^A = 6$ . Let demand in country A be defined relative to country B,

$$(2) \quad x_A(p_A) = 10s - tp_A$$

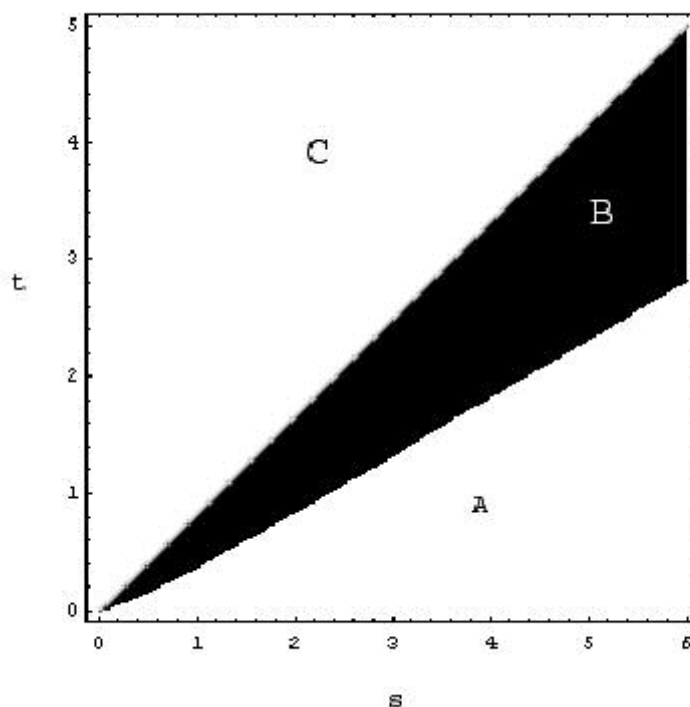
Here, the ratio  $s/t$  represents the relative “choke price” in market A, the maximum price any

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international price referencing practices.



Figure 1.



consumer is willing to pay for a unit of  $x$ . A larger ratio, represented graphically in Figure 1 by a less steep slope, corresponds to a higher choke price. For a given ratio  $s/t$ , a larger sort represents a larger market. In autarky, price in country A is a function only of the choke price:  $p_A^A = 5s/t + 1$ .

If country A allows parallel importation, prices will equalize to within trade costs, which in this example are set to 1. Prices in both countries will then be determined by the average of the choke prices, weighted by the relative size of the markets, plus or minus a margin accounting for the trade costs:

$$(3a) \quad p_B^T = 1 + 5(1+s)/(1+t) - t/(t+1)$$

$$(3b) \quad p_A^T = 1 + 5(1+s)/(1+t) + 1/(t+1)$$

In order for the difference in autarkic prices to be greater than trade costs, the choke price in

country A must be sufficiently high:

$$(4) \quad s > 6t/5$$

In figure 1, this condition holds in areas A and B. One additional condition determines whether parallel imports will cause any reduction in  $p_A$ . If the profit in country A under autarky is greater than the sum of the profits in both countries under parallel trade, the monopolist will choose to supply market A at the original discriminatory price, and set  $p_B$  equal to  $p_A^A$  minus the trade costs. At this price, market B may go unserved entirely, and market A achieves no price reduction from permitting parallel imports. The lower bound of area B in figure 1 represents this constraint.<sup>12</sup> Only for  $s$  and  $t$  values falling within area B will parallel imports cause any price reduction in market A. As can be seen, the area represents a fairly narrow range of values for  $s/t$ , and therefore a limited range of choke prices. Because the lower bound is concave up, the range of possible choke prices decreases as the size of the market increases. Thus, very small economies can achieve price reduction even if their choke prices (and therefore their autarkic prices) are comparatively high. New Zealand, which allows parallel importation, probably gains reduced prices because of its small size. Large economies may gain nothing at all by opening to parallel importation but could nonetheless cause other markets to go unserved.

This result should be qualified in a number of ways. Ganslandt and Maskus (2002) present a theoretic argument and empirical evidence that some of the assumptions about drug prices in our model of parallel importation do not always hold in reality. The authors describe a more sophisticated model of parallel importation than the ones sketched above, incorporating the

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<sup>12</sup>The curve, plotted using Mathematica, represents a long implicit function:

$$p_A^A x_A^A = p_B^T x_B^T + p_A^T x_A^T$$

possibility of endogenously limiting parallel importation. They imagine a high-priced market A, open to parallel imports, and a low-priced market B, from which parallel trade flows. It is likely that a manufacturer may try to limit the supply of drugs to market B if parallel exports are occurring. If the manufacturer can constrain the quantity of parallel trade by carefully regulating supply to market B, the possibility of parallel imports would not necessitate setting prices equal within trade margins. Instead, the manufacturer may choose to accommodate parallel imports by slightly lowering price in market A and allowing the limited quantity of parallel imports to be sold, rather than lower price enough to deter parallel trade entirely. The model allows for the possibility of parallel importation flows in equilibrium, instead of assuming that prices will equalize to within trade costs due to the mere potential for arbitrage.

Turning to empirical observations, the authors examined data from a natural experiment in Sweden, studying the effect on pharmaceutical prices before and after the nation opened to parallel importation. They observe that the price of a parallel imported drug does not fully equalize with the domestic counterpart, noting that there are perceived quality differences between parallel imports and domestically marketed drugs<sup>13</sup>. Additionally, they test whether price reductions of products facing competition from parallel imports occur because of the potential for arbitrage, as predicted by the standard model, or because of actual arbitrage, as predicted by their model incorporating accommodation. They find negative effects on prices for both potential and actual arbitrage, but only actual arbitrage is significant. The mere potential for parallel importation may not be enough to cause prices to converge.

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<sup>13</sup>It seems logical that pharmaceutical firms would seek to differentiate domestically marketed goods from parallel imports in any way possible. Often, parallel imports do not have the valid warranty offered by domestic goods.

Based on their model and evidence, the authors conclude that, if parallel importation is to be allowed, countries should ensure that their import markets are competitive. Examining the Swedish market, they find that parallel importers collect a large part of the price difference between countries as profit. Since the original justification for allowing prices higher than marginal costs is to promote innovation, any profit earned by traders can be viewed as pure inefficiency, not at all contributing to dynamic efficiency. Perhaps the fact that small trade-based economies such as Singapore and Hong Kong are open to parallel trade is due in part to the competitiveness of their import markets.

Several other caveats having to do with the causes of international price differences bear on whether parallel imports will be an effective policy tool. As discussed above, income inequality within a market can lead a firm to supply only a small, wealthy group of consumers, leaving lower income groups unserved. In such a situation, whether price reductions from parallel trade will have much of an effect depends on the size of the reductions. If price is not reduced beyond the kink in the demand curve, the wealthy minority would benefit from lower prices achieved through parallel imports, but consumers at lower income levels will still be left unserved. If a manufacturer can limit supplies, it would be difficult to obtain a quantity of drugs for importation large enough to serve lower income market segments.

Also noted above, reference pricing can lead to higher -than-proportionate price levels in countries which are reference priced. Allowing parallel imports would cause less of a price decrease in a referenced country than in an unreferenced but otherwise identical country, because decreases in price in the referenced country may necessitate a decrease in price in the referencing country. Essentially, the referenced country would bear more than its own weight in determining the price under parallel trade, making price decreases smaller and externalities more

likely and larger.<sup>14</sup>

It is often suggested that direct price regulations can be made more effective by using the threat of parallel import to negotiate lower prices from pharmaceutical firms. The strategy might be particularly effective in small economies, which do not have the same monopoly power as government health programs in large markets, and where parallel imports would bring greater price reductions if allowed. However, allowing parallel imports *from* countries that regulate prices would effectively pit one regulatory system against another, making price negotiations in the exporting country more difficult. If a manufacturer tries to limit supplies in the exporting country in order to impede parallel trade, shortages may also ensue. Allowing parallel trade would be most effective in small countries with weak regulatory systems, where parallel imports could allow the country to take advantage of prices in larger, more regulated markets.

Similarly, allowing parallel imports could let a country weaken the strength of patent protection for pharmaceuticals, if it is deemed overly strong. Patent systems vary in the scope and effective length of protection offered, affecting the amount and timing of competition. If, for example, a product is subject to generic competition in one country because the patent has expired, the price will be lower than in a country where the product is still on patent. The price difference created by the timing of patent expirations would create an opportunity for parallel importation, lowering the price in the country with stronger patent protection. As developing countries update their intellectual property regimes to comply with the standards of TRIPS, permitting parallel imports may be one method for moderating the strength of patent protection

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<sup>14</sup>New Zealand, Argentina, and Israel, all countries which permit parallel importation,

in the pharmaceutical sector.

In summary, allowing parallel importation will be an effective policy only under certain circumstances. Most basically, if the importing market is small, greater price reductions can be achieved through parallel imports. If a country can ensure competition among importers, price reductions will be greater. If a country has a weak regulatory system or an overly protective patents system, allowing parallel imports may help strengthen the negotiating power of the regulators or weaken the power of patents. If a country is not concerned with preserving high incentives for marketing and monitoring systems within its borders, parallel imports can help moderate prices. Under these conditions, allowing parallel imports could moderate drug prices, helping a country find a better balance of allocative and dynamic efficiency in its pharmaceutical markets.

### **VIII. Conclusions**

Thus far this paper has considered theories about the effects of parallel importation, including possible detrimental externalities, evidence concerning international price differences that create the possibility for parallel importation, and qualifications on the effectiveness of parallel imports. TRIPS left the parallel importation policy decision as a national prerogative, despite possible externalities that could leave some markets unserved. Recently, numerous policy recommendations have pushed for developed countries to prohibit parallel imports; for example, the British Commission on Intellectual Property Rights (2002) proposes:

Developed countries should maintain and strengthen their legislative regime to prevent import of low priced pharmaceutical products originating from developing countries... Developing countries should not eliminate potential

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are also all reference priced (Schoonveld 2001).

sources of low cost imports, from other developing or developed countries...  
 Developing countries should aim to facilitate parallel imports in their legislation.

They recommend preventing parallel imports from the developing world in order to facilitate differential pricing and improve access to pharmaceuticals in the developing world. However, encouraging developing countries to make use of parallel imports has only limited potential to control prices in developing countries. Where prices in developing countries exceed those in the developed world, parallel imports may moderate the disparity. Allowing parallel imports to flow within the developing world, though, presents the same potential for externalities. Countries in the developing world that are able to institute effective price control regimes would find it harder to negotiate prices, and might face supply shortages, if higher priced developing countries open to parallel importation. If individual developing nations open to parallel importation, any progress made in attaining lower prices could be shared by those nations, but the weight of their markets will make that progress all the more difficult to attain.

In order to improve access to pharmaceutical products, many strategies other than allowing or prohibiting parallel importation need to be pursued. Economic disparities within a country can lead to higher prices and limited access for poorer consumers, even though firms may still be pursuing strict differential pricing internationally. Methods for differentiating between consumers within the same national borders need to be found in order to truly improve access to pharmaceuticals. Differentiation is also in the interest of manufacturers, since selling at any price greater than marginal cost makes some contribution to recovering sunk costs and improving dynamic efficiency.

Some progress has been made in improving the supply of drugs to developing countries. A number of pharmaceutical firms have begun to offer price reductions in developing countries

when they can ensure that parallel trade to higher priced markets will not occur. By targeting discounts to governments, international charities and aid organizations, and to some extent large employers, firms can provide life -saving treatments for epidemic such as HIV/AIDS, while ensuring that the drugs will be used and not resold.<sup>15</sup> Many of these discounts are targeted specifically at Sub -Saharan Africa and/or designated least -developed countries (MSF 2002). Drug donation programs linked with tax incentives provide another method of improving access, but are a palliative, not a long -term solution (Maskus 2002). Other methods for differentiation in countries with high degrees of inequality need to be sought. Allowing parallel importation, as has been seen, can moderate prices only under limited circumstances. Preventing parallel importation and allowing market segmentation, though, will not necessarily lead to the equitable ideal of differential pricing, because many factors other than income differences are at work in determining pharmaceutical prices.

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<sup>15</sup>For a discussion of rebate strategies which could facilitate market segmentation and differential pricing, see Danzon (1997).



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